invention must have the same properties."

This rejection is respectfully traversed. In stating that "the instant invention must have the same properties" as the invention claimed in the 577' patent, it appears that the Examiner is of the opinion that a composition encompassed by the '577 patent must inherently possess the claimed pharmacokinetic parameters recited in the claims of the present invention.

With respect to the doctrine of inherency, it is noted that as set forth in the MPEP, 8th edition, section 2122, the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. In re Rijckaert, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); In re Oelrich, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be recognized by one of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999).

It is further set forth in the MPEP, 8th edition, section 2122 that "[i]n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the alleged inherent characteristic necessarily flows from the teachings of the applied prior art." Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. And Inter. 1990) (emphasis in original).

Further, the Federal Circuit stated the following in *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1268-69, 20 U.S.P.Q.2d 1746, 1749 (Fed. Cir. 1991):

Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient.

In view of the above, it is submitted that a composition encompassed by the claims of the '577 patent would not necessarily possess the same characteristics as recited in the claims of the present application. Accordingly, it is improper for the Examiner to state that "the instant invention must have the same properties" (emphasis added) as the invention claimed in the 577' patent and the obvious-type double patenting rejection should be removed.

REJECTION UNDER 35 U.S.C.§ 102(e)

In the Advisory Action, the Examiner maintained her rejection of claims 6-15 and 18-19 under 35 U.S.C. § 102(e) as being anticipated by Paradissis, et al. (U.S. Patent No. 5,133,974, hereinafter "the '974 patent"). The Examiner stated "Regarding Applicants' arguments of the 'controlled release matrix',... the term 'controlled release matrix' encompasses the extended release particles disclosed by Paradissis et al."

This rejection is respectfully traversed. The controlled release particles described in the '974 patent do not encompass controlled release matrix formulations. The '974 patent describes extended release formulations comprising: (i) from 0 to 50% of immediate release particles containing a core of drug, inert spherical substrate particles and binder, coated with talc; and (ii) up to 100% of an extended release particle comprising the immediate release particle coated with a dissolution modifying system (See: col. 3, lines 21-28). In contrast, the present claims recite, in pertinent part, an opioid analgesic contained in a controlled-release matrix, as opposed to the coated immediate release drug particles of Paradissis et al.

Further, regardless of the structure of the dosage forms recited in the claimed methods, the Paradissis reference does not exemplify opioid analgesic formulations, and it is respectfully submitted that there is no hint or suggestion in this reference of the presently claimed method of

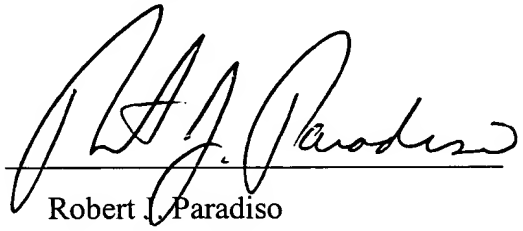
treatment having the specified pharmacokinetic parameters. Accordingly, the Examiner's rejection under 35 U.S.C. § 102(e) should be removed.

CONCLUSION

Applicants respectfully submit that the arguments presented above overcome the Examiner's rejections and that the pending claims are in condition for allowance. An early an favorable action on the merits is earnestly solicited.

Respectfully submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

By: 

Robert J. Paradiso
Reg. No. 41,240

Davidson, Davidson & Kappel, LLC
485 Seventh Avenue, 14th Floor
New York, New York 10018
(212) 736-1940